

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

DIRECT MARKETING CONCEPTS, INC., et
al,

Defendants

CIVIL ACTION NO. 04-CV 11136GAO

AFFIDAVIT OF MICHAEL SCIUCCO

I, Michael Sciucco, under oath declare as follows:

1. I am a member in good standing of the Massachusetts Bar and General Counsel of Direct Marketing Concepts, Inc. and ITV Direct, Inc. (collectively "ITV"). I submit the foregoing affidavit in further opposition to the Federal Trade Commission's motion to modify the Preliminary Injunction entered on June 23, 2004.
2. I have read the Federal Trade Commission's ("FTC") supplemental memorandum in support of its motion. I am troubled by the FTC's misrepresentations and omissions of the facts in its effort to impose a receiver upon ITV and effectively shut down the operations of the business.

ERSP

3. The Electronic Retailing Association ("ERA"), a private trade organization, in conjunction with the National Advertising Review Council (NARC), has created the Electronic Retailing Self Regulation Program ("ERSP"). The

ERSP's stated purpose is to "provide a quick and effective mechanism for evaluating, investigating, analyzing and resolving inquiries regarding the truthfulness and accuracy of...direct response advertising." However, during ITV's participation in this process, it became clear that the ERSP, although created by NARC, is an organization which is essentially one attorney, Peter Marinello, who reviews all advertising in the ERSP, amounting to thousands of advertisements. This one individual has been given sole discretion and authority to determine whether such advertising meets his subjective analysis of what "he" personally thinks is proper and scientifically substantiated.

4. During the course of my dealings with him, Mr. Marinello admitted that he did not have a scientific background. This lack of scientific training became abundantly clear in connection with his review of the Renuva product. For example, he repeatedly referred to the existence of HGH in Renuva, despite the fact that the advertisement clearly describes the product as an amino acid product and despite the fact that I notified him on several occasions that Renuva does not contain HGH. These communications also made clear that Mr. Marinello apparently did not read – or understand – the Renuva studies we provided, on the actual ingredients of Renuva. Tellingly, the FTC also quoted the ERSP findings in this regard, similarly indicating that Renuva contains HGH.¹ These simple mistakes by the ERSP and the FTC demonstrate the fundamental flaw in having non-scientists make decisions about substantiation in connection with dietary supplements. This

¹ Page 9 of the FTC's Reply Memorandum submitted on June 23, 2005.

misstatement by the FTC also appears to confirm that the FTC did not review any of the actual science in connection with the Renuva product.

5. Because of Mr. Marinello's unwillingness to acknowledge the actual scientific support for Renuva and its ingredients, and his insistence that we conduct a study on the product itself, we commissioned pilot study on the Renuva products as formulated. Contrary to both the FTC's and ERSP's position, that study, clearly demonstrates with statistical significance that the product is comparable to that of injectable forms of HGH.²
6. As it became increasingly clear to ITV, the overall ERSP process is fundamentally flawed, particularly in connection with reviewing scientific studies and evidence submitted to the ERSP. Critically, there is no appeal process, there is no scientist or medical expert on staff, and the ERSP guidelines are ambiguous and vague concerning the standard of substantiation applied by Mr. Marinello. The new Chair of the ERA has acknowledged fundamental flaws of the ERSP, and proposed significant changes to the ERSP process.
7. Due to the ERSP's meager staff and the lack of any scientists to review the vast substantiation submitted by participants, it is impossible for a single ERSP attorney to determine if the claims are substantiated for a product like Sea Vegg or Renuva.

² Due to the proprietary nature of this study, and the possibility of publishing this study, Anti-Aging Formulas LLC has requested that we refrain from submitting the study unless the study is filed under seal and all parties agree to maintain the confidentiality of the study. If the Court requests, we will undertake efforts to file the document under seal for the Court's review.

8. In addition to his misstatements concerning the scientific literature and ingredients in the products, Mr. Marinello also repeatedly misquoted statements made in the Sea Vegg advertisements. In virtually all of his letters to ITV, he asserted that statements were made in the advertising that were not made. Once again, the FTC has relied upon these misstatements in its Reply Brief, failing to review the actual advertising itself to determine if Mr. Marinello's assertions have any actual factual support. The FTC's heavy reliance upon the incorrect assertions of a non-scientist attorney from a private trade association to support alleged violations of federal law by ITV is remarkable, and demonstrates the FTC's inability to independently challenge the subject advertising.³
9. The FTC has alleged that ITV refused to work with ERSP in connection with the Sea Vegg advertisement. This is simply not true.
10. As set forth in the ERSP procedures, ITV forwarded ERSP thousands of pages of documentation, including scientific journals and studies, and similar scientific information, in support of the Sea Vegg advertising.
11. Demonstrating ITV's initial willingness to work with Mr. Marinello, we removed a number of demonstrably *truthful* statements from our website, notwithstanding that Mr. Marinello was unable to articulate any justification other than his subjective beliefs for why such information was problematic.

³ In two letters sent to ERSP submitted in my June 6th affidavit as exhibit's 13 and 15 respectively I informed Mr. Marinello of his numerous errors. If the FTC had independently reviewed the studies and the transcript of the advertisement they would have determined that the term "carcinogenesis" was never mentioned in advertisement and only discussed in studies presented to the ERSP. Therefore, the assertion by both ERSP and the FTC that a claim was made in the advertisement relating to the inhibition of carcinogenesis is categorically false.

Because of our growing concerns with the process, we stated that we would *consider* Mr. Marinello's other recommendations, subject to further review and discussion with him.

12. Many of Mr. Marinello's objections related to statements that we could easily prove to be true. For example, Mr. Marinello objected to such statements as "Scientific agreement behind my message and my mission." The scientific data produced clearly substantiates such a statement. Nonetheless, he maintained his objection and refused to acknowledge that such a statement was substantiated.
13. Despite our fundamental differences of opinion, ITV nonetheless made significant modifications to the Sea Vegg advertisement, including editing content and adding additional disclaimers, in an effort to comply with the ERSP's demands, while maintaining throughout that the statements were truthful and non-misleading, and supported by vast amounts of scientific evidence.
14. After making these modifications, and prior to receiving a "compliance" inquiry from the ERSP regarding our editing, we immediately began to air the newly edited version of the Sea Vegg advertisement. (See Exhibit 1)
15. Upon receiving this further "compliance" inquiry from Mr. Marinello, we forwarded the edited program along with a detailed explanation of the edits. (See Exhibit 2)
16. Mr. Marinello responded by stating that although he appreciated ITV's efforts, the changes were not enough. At this point it became clear that the process

with the ERSP was no longer meaningful and the ERSP was no longer the forum to discuss the advertisement. In our view, Mr. Marinello had concluded that no edits would be sufficient to satisfy him, and he had determined that the only solution was to prohibit altogether the airing of the advertisement, in any form.

17. Throughout the process we informed the ERSP several times that we were involved with ongoing litigation with the FTC. Because of this ongoing litigation, we requested that they dismiss the case as provided in the ERSP published policies. Despite informing Mr. Marinello of the FTC's involvement, he refused to terminate the ERSP process.
18. The FTC has claimed that I was aware of the ERSP findings prior to submitting my previous affidavit to the Court. That is not true. As demonstrated by the attached email (See Exhibit 3), I did not review Mr. Marinello's findings until *after* my affidavit was filed. Even so, we continued to object to the ERSP findings and sought to continue to work with them to revisit certain fundamental and demonstrable problems underpinning their conclusions.
19. In my correspondence and communications with the ERSP, I never used the pending federal litigation as a "shield" to the ERSP process. Rather, Mr. Marinello had made up his mind from the beginning and alluded to the fact early on in the process that he was going to refer the advertisement to the FTC, irregardless of our efforts to comply with his ever-changing demands. In our conversations, I notified him that the FTC had already submitted the

Sea Vegg advertisement to the federal court in connection with existing litigation as part of its efforts to appoint a receiver. Because he was unable throughout the process to articulate the standard under which he was reviewing ITV's substantiation for the advertising, I informed him that the matter was better reviewed and decided by a federal court and the FTC, which would be provided all of the materials submitted to the ERSP, as well as additional materials. Tellingly, when we offered to provide the ERSP with the additional information that we had provided to the Court and the FTC in support of the advertising, including Dr. Teas' affidavit, Mr. Marinello did not respond. This fact was conveniently omitted by the FTC in their supplemental submission.

20. The FTC also neglected to inform this Court of the substantial edits that were made by ITV in direct response to the ERSP recommendations. For instance, ERSP recommended that: "... the marketer ...clearly communicate that its scientific research: a) is limited to the seaweed and b) should not be construed as meaning that consumers should expect the ingredients, as they are contained in Sea Vegg, to provide the same benefits, *ERSP does not object to the references to the scientific research on seaweed*".
21. In addition to our multiple edits to the advertisement, ITV responded by adding additional disclaimers at the beginning and the end of the advertisement, as follows: "**Scientific research referenced in this program is limited to seaweed and its naturally occurring ingredients. Results with Sea Vegg™ will vary.**" Several times throughout the advertisement, we

also added the disclaimer: **“Scientific research referenced in this program is limited to seaweed and its naturally occurring ingredients.”** These added disclaimers were ignored entirely by the FTC in its most recent submission to this Court.

22. Although the FTC has stated that I mischaracterized statements by Mr. Marinello with regard to his acknowledgement of “competent” and “reliable” scientific evidence submitted by ITV, the ERSP did recognize “the volume of evidence and scientific research on many of the ingredients in seaweed.” Likewise, the ERSP acknowledged that “ITV provided ERSP with an abundance of information on the benefits of seaweed,” and “there is a tremendous amount of scientific documentation on seaweed and the potential therapeutic qualities it possesses.” In my view, I understood these statements to constitute an acknowledgement that the scientific evidence gathered and relied upon by ITV was both “competent” and “reliable” as it relates to the health benefits of seaweed.
23. The assertion by the FTC that I somehow “retracted” any statements is incorrect. ITV did disseminate the edited version of the Sea Vegg advertising, and intended to disseminate that version to all media stations. However, before the edited version was disseminated to all of the stations, and as I stated earlier, Mr. Marinello claimed that our efforts were not sufficient and raised additional claims concerning the advertisement, which he had never previously raised. It became clear that Mr. Marinello would not acquiesce unless ITV agreed to cease running any version whatsoever of the Sea Vegg

advertisement in question, regardless of the volume and detail of substantiation provided, the disclaimers added by ITV, and further edits as to content.

24. Likewise, although ITV disagreed with the ERSP regarding the Renuva advertising, ITV ceased running the Renuva advertisement after reviewing the ERSP's recommendations. Contrary to the FTC's arguments, and another glaring flaw in the ERSP process, the ERSP places no time frame for when such advertising should be completely removed. Nonetheless, we replaced existing Renuva media buys with other advertising as soon as practicable and reasonable. Once it was taken off the air, the advertising has not run since that date. The FTC's contentions to the contrary are without any basis.
25. Notwithstanding ERSP's purpose, which was established to serve as a forum to review advertising *outside* of government interference, ERSP nonetheless referred the Renuva advertisement to the FTC, even though I had informed Peter Marinello that ITV would no longer air the advertising and that the Renuva advertising had already been discussed by the FTC in the present litigation.
26. In addition to our growing concerns regarding the ERSP's apparent acts of bad faith and efforts to halt all advertising of any kind for Sea Vegg and Renuva, we took issue with the ERSP's violations of its own policies and procedures. Specifically, the ERSP rules state that: "to ensure the integrity and cooperative nature of the review process, participants must agree (i) to keep the proceedings confidential" which presumably would be all materials

submitted by participants, including correspondence. Mr. Marinello personally guaranteed that all of my correspondence and communications with him would be kept confidential. Nonetheless, we have learned that a number of third parties, including the FTC, have communicated with Mr. Marinello. In the course of these conversations, he has disclosed information he promised would be kept confidential, undermining the entire process. Such information has subsequently been used by the FTC in connection with the present motion.

27. Compounding the problems with the ERSP process, in recent weeks ERSP in conjunction with the Electronic Retailers Association (“ERA”) has sent out at least three false and misleading press releases in an attempt to harm ITV’s business, which also violate its own policies. These press releases falsely state that ITV refused to modify its advertising in accordance with the ERSP’s suggestions, which is demonstrably untrue.
28. Because ITV did not agree to pull entirely its advertisement for Sea Vegg, notwithstanding that the advertisement is supported by “competent and reliable scientific evidence” and is protected commercial speech, ITV was recently expelled from the ERA for its alleged noncompliance. ITV has no ability to appeal this decision, nor does it have any redress other than suing the ERA, which it is contemplating.
29. The FTC has raised concerns with alleged representations that I made to ERSP regarding ITV’s current dispute with the FTC. Notwithstanding my choice of words, Mr. Marinello was well aware of ITV’s pending litigation

with the FTC, and the public filings made by both parties in the case. Because it was clear Mr. Marinello would not accept any of our modifications, I informed him the only proper forum for discussing the advertisement for Sea Vegg was the federal court or the FTC administrative process.

Notwithstanding these conversations and my suggestion that ITV's due process rights were better served by having the federal court evaluate the advertising, the ERSP nonetheless proceeded to publish its findings and issue damaging press releases regarding ITV and the Sea Vegg advertising.

30. The FTC has accused ITV of being "unwilling" or "unable" to make substantiated claims. The evidence submitted by ITV demonstrates that the FTC's accusation is entirely without basis. Each of ITV's advertisements is supported by scientific evidence concerning the product. Prior to filing the present motion and supplemental brief, the FTC never requested ITV to provide its substantiation so that it could actually be reviewed by the FTC. The FTC's position that the claims are not substantiated is simply not credible in the absence of this review.

31. Despite the FTC's statements to the contrary, ITV is determined to conduct its business in conformity with the FTC Act and sound business practices. All of ITV's advertising is subject to strict review for content, is required to have clear disclaimers and must meet strict substantiation standards. Every advertiser who approaches ITV is told up front that they must supply ITV with adequate substantiation for the product, or ITV will not run the

advertising. Numerous products have been rejected by ITV for failing to provide adequate and reliable scientific support.

Sale Practices

32. As I stated in my affidavit submitted on June 6, 2005, ITV is committed to ensuring compliance in all aspects of its business. In that affidavit I attached a guide to ethical sales practices⁴ that I disseminated to the sales staff as part of ongoing training provided to them. In recent months I have improved on that training and created a more comprehensive presentation. This training, which addresses all of the issues raised by the FTC, is provided to sales managers and has been presented to the sales staff. (See Exhibit 4)

Independent Distributors

33. As has been explained previously to the Court and the FTC, ITV's distributors are independent companies with independent management and are not owned or controlled ITV. Nonetheless, as required by the Court's order, within 10 days of entering the order, ITV distributed copies of the Court's order to their distributors and, when ITV has become aware of statements made by distributors that ITV objects to, ITV has contacted those distributors to request that the statements be removed or modified.

Flex Protex

34. Flex Protex is a product that was developed by a publicly traded company, Nutracea, for joint and cartilage pain and inflammation associated with arthritis. Nutracea and its staff of scientists have spent several years and over

⁴ Exhibit 23 attached to my June 3rd affidavit.

\$50 million developing their products and substantiating their health benefits, including conducting clinical trials and receiving six patents on its products.

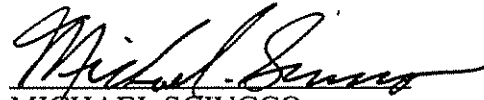
35. Contrary to the claims made by the FTC, Flex Protex is not a “greens” product, nor is it substantially similar – or similar at all – to Supreme Greens with MSM. Supreme Greens is a product comprised of roughly 42 green leafy vegetables and designed to supplement the diet for overall health. Flex Protex is a rice based product that has only eight ingredients with very specific intended use. In addition, forms of MSM are naturally occurring in almost all vegetables and plant based products. The existence of one form of MSM in one product does not render that product substantially similar to all other vegetable and plant base products that contain another form of MSM. Consequently, although both products are dietary supplements, they are otherwise entirely different products with different structures, core ingredients and intended uses.
36. We have compiled roughly two hundred (200) scientific studies and research papers substantiating each and every “claim” in the Flex Protex advertising. We have also consulted with Nutracea’s on staff PhD’s who have supported the efficacy of the product, and provided us with a wealth of scientific literature and studies.
37. In addition, as with Sea Vegg, the disclaimers in the Flex Protex advertising exceed those required by the Court’s prior order and make clear that the product is not intended to prevent, treat or cure any disease.

38. The FTC never contacted me or anyone else at ITV in connection with the Flex Protex advertisement. Had the FTC done so, ITV would have provided them with the vast amounts of substantiation for the “claims” in the advertisement and would have discussed the advertisement with the FTC in light of that substantiation.
39. The FTC admits that it has conducted no scientific analysis of the Flex Protex product or advertising. The FTC has provided no testimony or facts to counter the substantial evidence gathered by ITV, including scientific research, journal articles and well controlled double blind studies.
40. The FTC also presents no evidence that the ingredients in Sea Vegg or Flex Protex are somehow harmful to users. They are not. Thousands of consumers have safely taken the ingredients in these products for years. In addition, the FTC fails to provide any affidavits or evidence from customers in which they claim that they were misled by any of the advertising for Sea Vegg or Flex Protex. To the contrary, ITV regularly receives positive correspondence and testimonials from customers regarding these products.
41. ITV has undertaken extraordinary efforts to assure that all of its present advertising complies with the FTC Act and is supported by competent and reliable scientific substantiation. Nonetheless, the FTC appears determined to reject all such advertising regardless of ITV’s efforts, and regardless of the volume of substantiation. The FTC’s position is inconsistent with Congress’ express findings in connection with the Dietary Supplement Health and Education Act that “there is a link between the ingestion of certain nutrients or

dietary supplements and the prevention of chronic diseases such as cancer, heart disease and osteoporosis,” and that consumers, not the federal government, “should be empowered to make choices about preventive health care programs based on data from scientific studies of health benefits related to particular dietary supplements.” The FTC’s challenges to ITV’s advertising turns these findings by Congress on their head.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 28th day of September, 2005 in Beverly, Massachusetts.


MICHAEL SCIUCCO